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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,454	10/19/2001	Robert E. Dudley	01917581	6787

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EXAMINER	
JIANG, SHAOJIA A	

ART UNIT	PAPER NUMBER
1617	17

DATE MAILED: 10/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/046,454	Applicant(s) DUDLEY ET AL.	
	Examiner Shaojia A Jiang	Art Unit 1617	

-- The MAILING DATE of this communication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *June 13, 2003, July 11, 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21,27,53-55,57,58,60-64 and 79-145* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21,27,53-55,57,58,60-64 and 79-145* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *14,15* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 13, 2003 has been entered.

This Office Action is a response to Applicant's request for continued examination (RCE) filed June 13, 2003 in Paper No. 10, and amendment filed June 13, 2003 in Paper No. 11 wherein claims 1 and 104 have been amended.

Applicant's supplemental amendment filed July 11, 2003 has been entered in Paper No. 16, wherein claims 146-152 are newly submitted.

It is noted that Applicant's amendment filed June 13, 2003 and supplemental amendment filed July 11, 2003 are unclear as to which claim has been amended previously, i.e., Claims 6-10, 12, 13, 15, 16, 18, and 20 have been amended in Paper No. 7 submitted December 12, 2002, but the most recent amendment does not reflect this by "previous amended"; further, i.e. Claim 1 has been amended at least three times so far.

Currently, claims 1-21, 27, 53-55, 57-58, 60-64, 79-145 and 146-152 are pending in this application.

Claims 1-21, 27, 53-55, 57-58, 60-64, and 79-145 have been examined on the merits herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21, 27, 53-55, 57-58, 60-64, and 79-145 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "male subject" in the instant claims renders claims 1-21, 27, 53-55, 57-58, 60-64, and 79-145 indefinite. As noted in MPEP 2111, during patent examination, claims are given their **broadest** reasonable interpretation. It is proper to use the specification to interpret what the applicant meant by a word or phrase recited in the claim, However, it is not proper to read limitations appearing in the specification into the claim when these limitations are not recited in the claim. See *In re Paulsen*, 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994) for example.

Therefore, The recitation a "male subject" is not clearly defined in the specification. It is unclear as to the meaning of the term "male subject" encompassed in the claims herein.

The recitations and the transitional phrase "testosterone comprises an enantiomer, a recemic mixture, a derivative, a base, or a salt thereof" employed in claims 27, 57 and 109, and 114-119, and "composition comprising" render claims 57, 60-61, 63-64, "the packet comprises" in claims 79 and 128, render these claims

indefinite since the transitional phrases "consisting essentially of" already recited in the base claims 1 and 104. Thus, the open transitional phrases, "comprising" in dependent claims herein are improper. The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997). See also MPEP 2111.03.

Moreover, the recitation, " an enantiomer, a recemic mixture, a derivative, a base, or a salt thereof " in claims 27, 57 and 109 render claims 27, 57 and 109 indefinite. The recitations, " an enantiomer, a recemic mixture, a derivative, a base, or a salt thereof " are not clearly defined in the specification. Hence, one of ordinary skill in the art could not interpret the metes and bounds of the patent protection desired as to " an enantiomer, a recemic mixture, a derivative, a base, or a salt thereof ", since one of ordinary skill in the art would clearly recognize many various groups possibly substituting testosterone. Therefore, the claim is indefinite as to the composition encompassed thereby.

Further, one of ordinary skill in the art would clearly acknowledge that testosterone is a single compound which is already recited in the base claims 1 and 104. Thus, the dependent claims 27, 57 and 109 reciting "an enantiomer, a recemic mixture, a derivative, a base, or a salt " of testosterone, are improper being broader than the independent claims 1 and 104.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-21, 27, 53-55, 57-58, 60-64, and 79-145 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 43-62 of the copending Application No. 10/098,232.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application are drawn to a method of treating hypogonadism in a male comprising administering the instant composition to a male subject.

The claim of the instant application is drawn to methods of treating, or reducing the risk of developing a depressive disorder in a hypogonadal male subject, i.e., a hypogonadal man.

One having ordinary skill in the art at the time the invention was made would clearly recognize that these methods between in the copending application and in the instant application are seen to substantially overlap because both have the same

method steps, i.e., administering the same composition herein to the same hypogonadal man.

Thus, the instant claims are seen to be anticipated by the claims 43-62 of copending Application No. 10/098,232.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
October 14, 2003